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SYNEYE.002A (formerly QLT.002A)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Legerton et al.	)	Group Art Unit 2873
Appl. No.	:	10/657,061	)	
Filed	:	September 5, 2003	)	
For	:	HYBRID CONTACT LENS	)	
		SYSTEM AND METHOD	)	
Examiner	:	Jessica T. Stultz	)	
			)	
			)	

DECLARATION OF DR. JAMES A. BOUCHER PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, James A. Boucher, declare and state as follows:

1. I am a United States citizen, and I reside at 1050 Granito Drive, Laramie, Wyoming 82072.

2. I am currently a Doctor of Optometry at Snowy Range Vision Center, 405 South 30<sup>th</sup> Street, Laramie, Wyoming, 82070, where I have worked continuously since August, 1966, and where my duties include general optometric practice with an emphasis in cornea and contact lenses. Prior to holding this position, I was an optometry officer in the United States Air Force for 3 years from 1961 to 1964 where my duties included optometric practice for military personnel and their dependants. From 1964 to 1966 I was a graduate student, teaching assistant and researcher at the Indiana University, School of Optometry in Bloomington, Indiana where I gained additional experience with contact lenses and research methodology. I have worked in the contact lens industry for the past 44 years.

3. I have a Doctorate in Optometry and a Bachelor of Science from Southern College of Optometry in Memphis, Tennessee, a Masters of Science degree in Physiological Optics from

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Indiana University, School of Optometry. I also hold two Honorary Doctorates of Ocular Science from the New England College of Optometry and the Southern College of Optometry.

4. Since 1966 I have been a member of the Wyoming Optometric Association and served as its President from 1976 to 1978. I have been a member of the American Optometric Association since 1961 and served as Chairman of the American Optometric Association's Contact Lens Section from 1986 to 1987. I served as a member and consultant of the United States Food & Drug Administration's Ophthalmic Devices Section from 1977 to 1995. For my FDA service I received the Harvey W. Wiley Medal / Food and Drug Administration Commissioner's Special Citation in 1995 for my outstanding service to the FDA in the contact lens field.

5. I served on the American National Standards Institute (ANSI) contact lens sub-committee where I assisted in developing the ANSI standards for contact lenses.

6. I have been a Fellow of the American Academy of Optometry since 1965 and a Diplomate of the Cornea and Contact Lens Section since 1993.

7. I served in the Wyoming House of Representatives from 1975 to 1977.

8. I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve the cornea and contact lenses. A list of my publications can be found in my CV which is attached hereto.

9. I currently serve as a consultant with SynergEyes, Inc, previously Quarter Lambda Technologies, Inc., the owner of the pending patent application. I am assisting SynergEyes, Inc. on, among other things, product development and clinical issues. I do not hold stock or any ownership interest in SynergEyes, Inc.

10. I have worked in the contact lens industry for the past 44 years, including the research and development of gas permeable and non-gas permeable rigid, hybrid and soft lenses. Further, I've been involved in research related to these types of lenses. I served as a Principal Investigator for FDA Class II pre market notification clinical trials of the SynergEyes™ high Dk hybrid lens for Quarter Lambda Technologies, Inc., the owner of the pending patent application. I have worked with the design and methods of fitting hybrid contact lenses and have knowledge of hybrid contact lens designs that have been commercialized. To the best of my knowledge all commercially available hybrid contact lenses have a low Dk center and low Dk skirt. I understand that a major problem with these commercial lenses is that they can separate at the junction between

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the hard center and the soft skirt. Other major problems of these lenses include low oxygen transmission to the eye, undesirable lens flexure and the failure of the design to provide tear exchange.

11. I have reviewed the pending claims in the above-identified application and the proposed amendment to the claims filed herewith. I have also reviewed U.S. Patent No. 6,043,328 ("Domschke") and GB Patent No. 1,417,650 ("Sohniges"), the two references I understand the Examiner has used to reject pending claims in the above-identified application as being obvious. I disagree that these claims are obvious in view of Domschke and Sohniges.

12. In my opinion, the combination of Domschke and Sohniges would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

13. Domschke does not disclose, teach or suggest a hybrid contact lens with a substantially rigid central portion having a Dk of at least  $30 \times 10^{-11}$  (cm<sup>2</sup>/sec) (mL O<sub>2</sub>)/(mL x mm Hg) and substantially flexible hydrophilic peripheral or annular portion coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid central portion. Instead, Domschke describes a polysiloxane-polyol macromer material, and contact lenses including said material. Domschke also discloses coating a surface of a lens with a hydrophilic material to improve the hydrophilicity of the lens. Indeed, there is no disclosure or suggestion in Domschke to provide a hydrophilic peripheral skirt, or bond a hydrophilic peripheral skirt to a rigid central portion. Domschke's single reference to a hybrid lens appears to refer to either (a) a lens with a rigid core section and a hydrophilic surface, (b) a rigid gas permeable lens with very high flexure, or (c) a soft lens made of a Silicon Elastomer (aka Silicon rubber) with no water content, all of which have been referred to at times in the contact lens industry as hybrid lenses because they exhibited some characteristics found in both soft and rigid gas permeable lenses (e.g., intermediate rigidity between that of a rigid gas permeable lens and that of a soft lens). However, none of these contact lenses (i.e., a lens with a rigid core section and a hydrophilic surface, a rigid gas permeable lens with very high flexure, or a soft lens with no water content) teach or suggest a contact lens having a substantially rigid central portion coupled to a substantially flexible hydrophilic peripheral portion, as recited in the amended claims of the above-identified application.

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14. With respect to Sohnges, the reference does not disclose a hybrid contact having a hard central portion with a Dk of at least  $30 \times 10^{-11}$ . In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high Dk central portion, 2) provide a hydrophilic skirt, or 3) bonding a high Dk central portion to a hydrophilic skirt in any manner. Therefore, one of skill in the art looking at these two references would not be able to combine the material of Domschke with the lens in Sohnges to obtain the claimed invention.

15. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision, movement of the lenses occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lenses with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture larger overall diameter lenses which conform more closely to the asymmetric surface of the eye. These lenses demonstrate less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of hard lenses.

16. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high DK providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as the late 1980's of attempts that have been made to manufacture an improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

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17. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past 44 years, I do not believe the claimed invention recited in the pending claims of the above-identified application are obvious in view of Domschke and Sohnges.

18. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: 01/27/06

  
James A. Boucher, OD, MS, FAAO

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